Producing and distributing effective field safety notices

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Keywords
Field safety corrective action (FSCA); Field safety notice (FSN); Field corrective action (FCA); MEDDEV 2.12/1 rev 8; Distribution; Targeting; Traceability; Medical device safety officer (MDSO).

Abstract
For manufacturers of medical devices, a field safety notice (FSN) is their primary means of informing their customers of a field safety corrective action (FSCA). As the competent authority for the UK, the MHRA receives notifications of FSCAs and the associated FSNs for medical devices that are on the UK market.

There are existing guidelines for writing and distributing FSNs in the European Commission’s document Medical Devices Vigilance System (MEDDEV 2.12/1 rev 8), which describes the European system for the notification and evaluation of incidents and field safety corrective actions (FSCA) involving medical devices.

In this article, we provide supplementary information to the MEDDEV and give advice on how to produce and distribute effective FSNs.

Introduction
In the UK, medical devices and in vitro diagnostics are currently regulated by three EU directives: Active Implantable Medical Devices directive;² In Vitro Diagnostic Medical Devices directive;³ and Medical Devices directive.² From 25 May 2017, the EU Medical Devices Regulations (MDR)⁴ and EU In Vitro Diagnostic Devices Regulation (IVDR)⁵ came into force, with a transition period of three years for the MDR and five years for the IVDR.

MEDDEV 2.12/1 rev 8, 2013 states: “A field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a field safety notice.”⁶

Are FSNs confidential?
Competent authorities (CAs) keep reports of adverse incidents confidential, as required by the directives. When a CA receives information from a manufacturer that identifies a field safety corrective action (FSCA) or a threat to patient safety, a lead CA is identified and this CA sends a notification (in confidence) to the other CAs in the EU, the European Commission and members of the International Medical Device Regulators Forum (IMDRF). This promotes coordinated action across Europe. Once a manufacturer has issued an FSN to customers, it is no longer treated as confidential because it is considered to be in the public domain.

Good traceability
Manufacturers should maintain records to help trace their distributed product. This should include:
- Records of medical devices by manufacturing date and batch or serial number
- Traceability of medical devices directly supplied to users and distributors.

Contracts with distributors should ensure that onward traceability records to end users are maintained as far as is practicable as this will help manufacturers to get maximum replies to their FSNs.

FSN content
The FSN should be written in a clear and concise style, at an appropriate level for the intended audience. Remember that in some cases patients will read the notice so it’s best to avoid jargon or unnecessary technical language.

The risk to the user is the key element of the notice. Manufacturers shouldn’t delay sending an FSN because they’re waiting to include information on the cause of the problem. In such circumstances, there is the option to send a follow-up FSN.

Section 5.4.4.2 of the MEDDEV describes the content of the FSN and Annex 5 has a simple template that manufacturers can use to write their FSN. The MHRA has been leading on a project to produce an updated, interactive template that should be available on the European Commission’s website later in 2018. Manufacturers have the option of sending their draft FSN to us for comment.

Some problems we’ve found in draft and published FSNs include:
- Missing lot numbers
- Too much jargon
- Badly explained or missing instructions on what to do next
- Missing detailed description of the problem
- Missing explanation of how the problem affects the patient
- Incorrect or missing contact details for the UK or EU
- Missing acknowledgment form
- Final FSN hasn’t been signed or dated
- Poor translations – we suggest asking your authorised representative or distributor in the UK to check the English.

Some hospitals require a signed and dated acknowledgment form from customers who receive the FSN. The MHRA requires an electronic, definitive, version of the FSN with the correct contact details for the UK or the EU. It must have
only generic information about the recipients so it must not be a sample with an individual’s name or address on it. Covering letters should also be included in the FSN. Our preference is to receive a single PDF file with all the relevant information rather than separate files with versions of FSNs such as one aimed at distributors and another at customers. The PDF must not be a scanned version of a paper document as this means it is not searchable for serial numbers etc.

We publish weekly lists of FSNs that affect the UK on our web pages (www.gov.uk/drug-device-alerts) which, although for information only, are extremely popular – there are more than 10,000 subscribers to these pages.

The manufacturer’s FSCA strategy
The FSCA strategy will need to specify whether a general, public warning (advertisement, a helpline number for 24-hour access to further information or media release) is needed and whether more specialised news media are to be used. The latter can allow targeting of specific segments of the population to prevent unnecessary public anxiety and advise that consultation between patients and their healthcare professional is essential.

Whichever method is used, manufacturers should inform the MHRA first and send us a draft copy for comment. There is advice on advertising and using the media in the PROSAFE Corrective Action Guide.7

Effective targeting of FSNs and maximising response rates
The FSN, with the crucial acknowledgement instructions, should be issued as soon as possible after the final version has been agreed. The MHRA doesn’t stipulate the method of distributing FSNs. The key element in maximising response rates is to make sure the right people know that the FSN is urgent and needs a response. A ‘read receipt’ of an email is not acceptable proof of acknowledgement of an FSN because it doesn’t prove that the FSN has been read and acted on.

Some companies are now using an e-signature portal as confirmation that FSNs have been received by and acted on by the organisation and we would encourage this route of distributing FSNs. Registered post only proves that the FSN arrived at its destination, not that it has been read and acted on by the intended recipient.

The MHRA often has to issue medical device alerts (MDAs)8 to remind users about FSNs because there hasn’t been enough feedback that it has reached the appropriate people and been acted on (often referred to as FSN reconciliation). One tactic to help get replies to FSNs is to use the network of medical device safety officers (MDSOs) in healthcare establishments throughout England.

The way to access the list of contacts is through an account with the MHRA’s manufacturer’s online reporting environment (MORE). With a MORE account, manufacturers can submit and manage their reports online, or just use the MDSO email lists to send FSNs. The list is updated monthly and includes the contact details for Scottish equipment coordinators.

MDSOs have to be registered with the MHRA and part of their role is to act as an additional senior point of contact for manufacturers and support local actions on FSNs. Although not all healthcare organisations have an MDSO, more than 95% of trusts do, so it is a great advantage to include MDSOs when sending FSNs to your customers.

The MHRA has a flyer on field safety notices9 that explains FSNs

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**Figure 1: MHRA’s FSN review and monitoring process.**

- **FSCA/FSN input and assigned to specialist**
- **Specialist conducts initial review of safety message and required actions**
- **Specialist may ask for more information from manufacturer or seek clinical opinion**
- **Information on reconciliation and long-term CAPA received from manufacturer**
- **Technical group meeting collectively reviews FSN**
- **Specialist may ask for more information from manufacturer or seek clinical opinion**
- **Specialist completes risk assessment including recommendations for MHRA actions relating to the FSCA**
- **Assessment is reviewed by the senior management**
- **Specialist fulfills the actions agreed, e.g., continue to monitor, publish MDA, etc**
The MHRA expects manufacturers to reply quickly to queries about FSCAs – delayed replies increase the likelihood of the MHRA publishing separate advice to the health service in the interests of protecting public health and why they are important, which manufacturers can send to their customers to help achieve target reconciliation on responses.

What does the MHRA do when there is an FSCA?

Where there is doubt, the MHRA will provide its interpretation of whether the action proposed by the manufacturer falls within the definition of an FSCA and will give advice on FSNs and associated FSCA strategies.

As soon as possible after we receive sufficient information from the manufacturer, the details of every FSCA are reviewed. The MHRA expects manufacturers to reply quickly to queries about FSCAs. Delayed replies increase the likelihood of the MHRA publishing separate advice to the health service in the interests of protecting public health. It may also lead to the MHRA initiating legal compliance action.

Circumstances where the MHRA might have to issue separate advice include the need to:

- Supplement information provided by the manufacturer, eg, when the message of the FSN is not clear or where additional advice is needed
- Bring the FSCA to the attention of a wider user base than that contacted directly by the manufacturer, eg, to target different or additional professionals
- Notify chief executives of NHS trusts or other management personnel, for reasons of clinical governance, of information being issued directly to healthcare professionals
- Issue an MHRA statement where a safety issue has a sufficiently high profile that the health service would expect it
- Help ensure the message gets to everyone affected when a very large number of customers and centres are affected, and/or where there is a possibility that devices may have been moved between healthcare providers/centres without the knowledge of the manufacturer or distributor
- Help speed up response to a manufacturer’s request for acknowledgement of receipt of an FSN
- Give different advice to that provided by the manufacturer, although through negotiation we try to avoid this wherever possible.

The manufacturer, or its authorised representative, will almost always get the opportunity to comment on the draft of any safety-related notice that the MHRA produces.

Circumstances where an MHRA safety-related notice may not be required include where there is high confidence that all potentially affected device users have been accurately identified and contacted by the manufacturer, and where the MHRA considers the information issued and action taken by the manufacturer to be sufficient.

For FSCAs with public, media or a particular health interest, the MHRA will liaise with colleagues in the Department of Health and with the manufacturer to prepare information for general release. Media statements should be worded to minimise any public alarm. Where necessary, UK health ministers will be kept informed.

The MHRA will agree appropriate milestones with the manufacturer or authorised representative for receiving FSCA status reports, including a final report. We examine all the reports from the manufacturer and keep an ongoing assessment of the effectiveness of the FSCA action. This may include further referral to the weekly technical management meeting.

Where an FSCA is initiated following a report of an incident submitted to the MHRA, we will communicate the outcome of the investigation to the person who sent us the report. In the interests of worldwide patient and user safety, and separate from obligations under the EC directives, the MHRA may also provide copies of MHRA safety warnings (eg, MDAs) issued to the health service in the UK to other regulatory authorities outside the EEA. (See Figure 1 for an illustration of the FSN review and monitoring process.)

What about field corrective actions?

The MHRA encourages manufacturers to deal with field corrective actions in a similar way to FSCAs, although they are outside the scope of the notification requirements of the medical devices directives.

A field corrective action (FCA) may arise from a more minor device-related safety issue that does not pose a risk of death or serious injury.

How to spot the difference between an FSCA and an FCA

Below are some examples of FSCAs involving different types of devices:

- **Example 1: Class IIa medical device (Heaf test).** Following reports that a device seemed to give an abnormally high level of “false negative results”, the manufacturer identified that, although it was performing to specification and requirements, the firing mechanism could be interrupted if it was not handled in a specific way. The instructions for use supplied with the device did not clearly identify this handling requirement. The manufacturer changed the instructions so that the handling of the unit was clearly highlighted in both text and diagram form. The manufacturer felt this was necessary due to the potential problem of misfired units giving rise to false negatives, which in turn could result in inappropriate tuberculosis immunisation. Therefore, the manufacturer not only amended the instructions for units still under manufacture, but also identified all units with users to ensure their instructions were similarly updated.

- **Example 2: Syringe pump alarm failure.** A manufacturer of a syringe pump identified a small risk that pumps within a range of serial numbers may not alarm if the syringe plunger clamp was left open, putting patients at risk from over- or under-infusion. The manufacturer issued instructions on detecting and correcting the problem. Instructions on checking the “Clamp Open” detection mechanism during routine maintenance were also added to the service manual.

- **Example 3: Active implantable medical device.** A manufacturer identified that due to a battery defect, the rate of battery depletion towards the end of service life of one of its pacemaker models was more rapid than originally anticipated through accelerated testing. There were no un-implanted units remaining with distributors or in hospital supplies available for return to the manufacturer. The manufacturer issued written advice to clinicians following
patients implanted with these pacemakers, emphasising the need to schedule clinic visits more frequently than indicated within the physicians’ manual supplied with the product to check the pacemaker battery status. Failure to detect early signs of battery depletion would risk the patient losing pacing therapy.

- Example 4: An in vitro diagnostic medical device. A test for detecting bacterial antigen in cerebrospinal fluid is found to cross-react with another bacterium which causes meningitis. This could result in the wrong antibiotics being administered. A full FSCA is initiated.

- Example 5: A device used in the community. Following reports of users falling from powered wheelchairs due to failures of castor assemblies, it was found that the instructions for use did not include adequate user checks and regular maintenance requirements to ensure that the castors could continue to operate correctly. The manufacturer revised the instructions for use and incorporated new requirements for user functional checks and regular maintenance.

Examples of FCAs are as follows:

- Example 1: General medical device. A manufacturer places an incorrect expiry date of 18 months on the labelling of a batch of product. The supported shelf life is two years. The manufacturer chooses to send new labels with the correct expiry date to customers.

- Example 2: Out-of-box failure. A product is shipped with a reagent missing. Users cannot run the test without it. The manufacturer exchanges distributed product for complete test kits.

Conclusion

Manufacturers should have a strategy for carrying out their FSCA so that it is as effective as possible. They should follow the guidelines available for producing effective FSNs and liaise with the relevant competent authorities where possible.

References